DETAILED ACTION

Response to Election/Restriction filed on June 23, 2008 is acknowledged. Claims 1-5 have been cancelled, and new claims 8-10 have been added. Claims 6-10 are pending in this application.

Restriction

1. Applicant's election of Group III (claims 6 and 7, and new claims 8-10) in the reply filed on June 23, 2008 is acknowledged. As described above, Applicant cancelled claims 1-5. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The Restriction requirement is still deemed proper and is made FINAL in this office action. Claims 6-10 are examined on the merits in this office action.

Claims Objections

2. Claims 6-8 are objected to for the following minor informality: the sequence identifiers used are not according to the US practice. The proper sequence identifier is SEQ ID NO: 1 (see MPEP 2422, 37 CFR 1.821 (d)). Applicant is advised to correct the errors.

3. Claims 7 and 9-10 are objected to for the following minor informality: Claim 7 is dependent on claim 1, which has been cancelled. A claim cannot be dependent on a

cancelled claim. Since claims 9-10 are dependent on claim 7, these claims are objected to for the above reason.

4. Claims 6-10 are objected to for the following minor informality: Claims as recited are unclear since the patient population is not known. For example, claim 6 recites, "A process for treating an individual for tinea including the step of administering to an individual a peptide…" It is unclear which individual the peptide is being administered to, such as those individuals already having tinea or will get tinea in the future. Claims 8 does not further specify the individual, therefore, it is also unclear. Claim 7 recites, "A process for controlling the growth of a fungus that is capable of causing tinea including the step of contacting a fungus that is capable of causing tinea with a peptide according to claim 1." Claim 9, which is dependent on claim 7 recites, "A process for controlling the growth of a fungus that is capable of causing tinea according to claim 7, wherein the peptide is administered topically to skin of the individual. Again, since it is unclear which individual the peptide is being administered to, such as those individuals already having tinea or will get tinea, the claims are unclear.

Rejection

35 U.S.C. 112, 2nd

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claims 6-10 are incomplete, since the claims don't specify the patient population.

7. Claim 6 recites, "A process for treating an individual for tinea including the step of administering to an individual a peptide…" The patient population is not known, therefore, the claims are incomplete. For example, it is unclear if the individual already has tinea or will get tinea in the future. It is unclear if the treatment is to those individuals already having symptoms of tinea or those predisposed to it. Because claim 8 depends from indefinite claim 6 and does not clarify the point of confusion, the dependent claim must also be rejected under 35 U.S.C. 112, second paragraph. By reciting "in need therefore" resolves the issue because it identifies the patient population.

8. Claim 7 recites, "A process for controlling the growth of fungus that is capable of causing tinea including the step of contacting a fungus that is capable of causing tinea with a peptide according to claim 1." Claim 9, which is dependent on claim 7 further recites, "wherein the peptide is administered topically to skin of the individual." The patient population is not known, therefore, the claims are incomplete. For example, it is unclear if the individual already has tinea or will get tinea in the future. It is unclear if the controlling of the growth of a fungus (capable of causing tinea) is to those individuals already having symptoms of tinea, or those predisposed to it. Because claims 9-10 depend from indefinite claim 7 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph. By reciting "in need thereof" resolves the issue because it identifies the patient population.

9. Claim 9 recites the limitation "the individual" in 2nd line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 9 is dependent on claim 7. Claim 7 recites, “A process for controlling the growth of a fungus that is capable of causing tinea including the step of contacting a fungus that is capable of causing tinea with a peptide according to claim 1.” Claim 7 does not recite the limitation “individual”. Therefore, claim 9 lacks antecedent basis.

Rejection

35 U.S.C. 112, 1st

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount

of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is drawn to a peptide suitable for treatment of tinea and to processes for producing peptides and compositions, for the treatment of tinea.

(2) The state of the prior art:

The Medical Library indicates that tinea is a general term for a group of related skin infections caused by different species of fungi; or a fungal infection characterized by ring-shaped, red, scaly or blistery patches (see p. 1, 1st paragraph, www.medem.com/medlb/article_detaillb.cfm?article_id=zzz8w2qju9c&sub_cat=296). There are different tinea infections: jock itch (tinea cruris), athlete's food (tinea pedis), tinea of the body (tinea corporis), face (tinea faciei) and scalp (tinea capitis) (see p.1, 1st paragraph). The Medical Library indicates that to obtain proper treatment, it is essential to distinguish tinea from other skin problems such as dermatitis or psoriasis; diagnosis is made through evaluating the appearance of the skin and tests such as a skin scraping (see p. 2, 1st paragraph of "Diagnosis and Treatment", www.medem.com/medlb/article_detaillb.cfm?article_id=zzz8w2qju9c&sub_cat=296).

American Osteopathic College of Dermatology (AOCD) indicates that there are excellent treatment for skin fungus infections that occur on the feet, nails, groin, hands and other locations. However, unfortunately, there is strong tendency for fungal infection to recur in many people even after effective clearing with medication (see p. 1, 1st paragraph, www.aocd.org/skin/dermatologic_diseases/fungus_preventing.html). Furthermore, AOCD indicates that especially on the feet and toenails, their skin cannot recognize the fungus as foreign and get rid of it, and after having a fungus there for a while, the body's immune system learns to live with the fungus and no longer tries to get rid of it (see p. 1, 2nd paragraph).

Merck manual indicates that different symptoms of tinea must be diagnosed first and treatment is considered (see pp. 2-5, Merck manual, "Dermatophytoses).

MayoClinic.com indicates that ringworm of the body is one of several forms of ringworm, a fungal infection that develops on the top layers of your skin. Ringworm of the body, is also called tinea corporis. MayoClinic.com indicates that other common tinea infections include athlete's food (tinea pedis), jock itch (tinea cruris), ringworm of the scalp (tinea capitis) (see p. 1, "definition", Ringworm of the body, www.mayoclinic.com/print/ringworm/DS00489/DSECTION=all&METHOD=print). MayoClinic.com indicates that the cause tinea is due to fungal infection by microorganisms that become parasites on your body (see p. 2, "Causes"). Further, MayoClinic.com indicates that a doctor will determine if you have ringworm or another skin disorder, such as psoriasis or atopic dermatitis, and will take skin scrapings or samples from the infected area (see p. 3, "Tests and diagnosis"). MayoClinic.com

indicates that there are several prescription-strength topical or oral medications; prevention of ringworm is difficult, because the fungus that causes ringworm is common and contagious even before symptoms appear (see p. 3-4, “Treatments and drugs” and “Prevention").

American Podiatry Medical Association (APMA) indicates that athlete's foot is a skin disease caused by a fungus, usually occurring between the toes. Fungus most commonly attacks the feet because shoes create a warm, dark and humid environment which encourages fungus growth. However, not all fungus conditions are athlete's food, such as disturbances of the sweat mechanism, reaction to dyes or adhesives in shoes, eczema, and psoriasis may mimic athlete’s foot (see p. 1, 1st-2nd and 4th paragraphs, www.apma.org/s_apma/doc.asp?CID=371&DID=9386). The APMA indicates that it is not easy to prevent athlete’s foot because it is usually contracted in dressing rooms, showers and swimming pool locker rooms where bare feet come in contact with the fungus (see p. 1, “Prevention”). The APMA indicates fungicidal and fungistatic chemicals, used for athlete’s foot treatment, frequently fail to contact the fungi in the horny layers of the skin, and therefore, topical or oral antifungal drugs are prescribed (see p. 2, “Treatment”). Furthermore, the APMA indicates that the podiatrist will determine if a fungus is the cause of the foot disorder/problems. Further, antifungal medication applied topically or taken by mouth appears to provide better resolution of the problem, when the patient observes the course of treatment prescribed by the podiatrist (see p. 2, “Consult Your Podiatrist”).

The art provide guidance that tinea must be diagnosed by a physician first before determining whether a patient has tinea or other skin disorder, such as psoriasis or atopic dermatitis. Furthermore, the art provide guidance that there are treatments available, but prevention is difficult. However, none of the prior arts provide guidance as how to determine individuals who are susceptible to tinea.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

Applicant's activity is based on the determination of predicting those who are susceptible to tinea. Since the activity is based on determining the patient population that is susceptible to tinea, the predictability in the art is low. This is due to the fact that the art has recognized the difficulty in determining the patient population who are susceptible to tinea.

The claims do not identify the patient population, therefore, the claims imply that anyone can be protected against tinea. Furthermore, since the claims do not identify the patient population, tinea can be prevented in everyone. However, the Applicant has not shown who will be susceptible to tinea and the population who need controlling the growth of a fungus that is capable of causing tinea. There are too many variables between the experimentation, thus, it clearly shows the unpredictability of the art.

(5) The breadth of the claims:

The claims are drawn to a method for treating an individual for tinea, comprising administering to an individual a peptide of SEQ ID NOS: 1-3. Further, the claims are drawn to a method for controlling the growth of a fungus that is capable of causing tinea comprising contacting a fungus that is capable of causing tinea with a peptide of SEQ ID NOS: 1-3, wherein the peptide is administered topically to skin of an individual. The claims do not define or identify the patient population, just an individual, so they imply that all individuals can be prevented from tinea. Furthermore, the claims recite, "capable of causing tinea". Capable of causing means/implies "prevention", since the patient must be predetermined to having the fungus before it can be capable of causing tinea.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples:

The specification provides guidance on reducing fungal growth using the peptides of SEQ ID NOS: 1-3 on test fungus (*M. canis, M. gypseum, T. tonsurans, T. rubrum and T. mentagrophytes*). Example 1 indicates that peptides were considered as showing a capacity to inhibit *M. canis*, *M. gypseum*, *T. tonsurans*, *T. Rubrum* and *T. mentagrophytes* when they showed greater than 50% and up to 97% inhibition of growth of the test fungus (see paragraphs [0138]-[0139] of instant specification US 2007/0129294 A1). Example 1 also describes spore germination assay on the same test fungus. Example 1 indicates that peptides were considered as showing a capacity to inhibit the test fungus when they showed greater than 50% and up to 97% inhibition

of the test fungus (see paragraphs [0141]-[0142] of the instant specification above). The specification does not describe prevention of tinea on any individuals. Thus, the specification provides guidance on how to measure the reduction in fungal growth, the specification does not disclose how to determine the patient population having the fungal infection, tinea. Additionally, it is unclear as to when the compound is to be administered and the patient population.

In order to prevent the infection of tinea or any other fungal infection, the patient population having those fungal growths must be predetermined. However, as indicated by arts, the diagnosis must be performed by a physician and must determine the tinea infection from other skin disorders. As indicated above, the Medical Library indicates that tinea is a general term for a group of related skin infections caused by different species of fungi; or a fungal infection characterized by ring-shaped, red, scaly or blistery patches (see p. 1, 1st paragraph, www.medem.com/medlb/article_detaillb.cfm?article_id=zzz8w2qju9c&sub_cat=296). There are different tinea infections: jock itch (tinea cruris), athlete's food (tinea pedis), tinea of the body (tinea corporis), face (tinea faciei) and scalp (tinea capitis) (see p.1, 1st paragraph). The Medical Library indicates that to obtain proper treatment, it is essential to distinguish tinea from other skin problems such as dermatitis or psoriasis; diagnosis is made through evaluating the appearance of the skin and tests such as a skin scraping (see p. 2, 1st paragraph of "Diagnosis and Treatment", www.medem.com/medlb/article_detaillb.cfm?article_id=zzz8w2qju9c&sub_cat=296).

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The art provide guidance that tinea must be diagnosed by a physician first before determining whether a patient has tinea or other skin disorder, such as psoriasis or atopic dermatitis. Furthermore, the art provide guidance that there are treatments available, but prevention is difficult. However, none of the prior arts provide guidance as how to determine individuals who are susceptible to tinea.

The specification has not provided guidance in the way of a disclosure to how to determine individuals that need protection against tinea and how to determine individuals requiring control of fungal growth that is capable of causing tinea. There is no clear guidance as to how to determine the patient population, since physicians need to determine the type of skin disorder after the infection or disorder is contacted, and a patient population is not defined, and it is unclear who would develop the tinea, more guidance is necessary. Since the prior art is still unclear as to who are susceptible to tinea, more guidance is necessary.

(8) The quantity of experimentation necessary:

Since it is uncertain to predict the patient population who are susceptible for tinea, and the Applicant have not provided the appropriate time frame at which the compound should be administered, and the Applicant have not provided guidance as how to measure the prevent tinea from all individuals, one of ordinary skill in the art would be burdened with undue “painstaking experimentation study” to determine if the peptides of SEQ ID NOS: 1-3 would be effective in protecting all individuals against

tinea and controlling the growth of fungus that is capable of causing tinea in all individuals.

Please note that the term "prevent" in an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat" or "alleviate", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes)-including preventing such infection as tinea, which is clearly not recognized in the medical art as being totally preventable condition.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654